

Altasciences helps accelerate the timeline from manufacture to clinical trial administration, starting at API availability. We discuss your program objectives early in the process, and proactively plan for success. With a clear understanding of compounding and dispensing needs, we can manage any complex changes that may arise, and ensure the availability of supply throughout your entire drug development program or single study.

SYNERGIES FROM MANUFACTURING TO CLINIC

- Tailored small batch preparations
- Advancing preclinical formulations to clinical
- GMP API availability
- Specific, study-related changes to formulation, route of administration, etc.
- Pharmacy compounded formulations can be modified, refined, and analytical methods validated, at our GMP manufacturing facility
- Single supplier with relevant licenses facilitates narcotics management

PHASE-APPROPRIATE MANUFACTURE

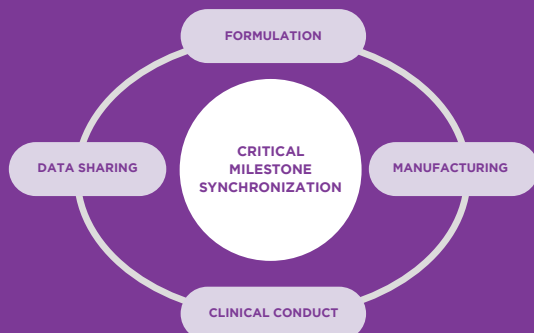
- Complex on-site pharmacy compounding, dispensing, and retention knowledge follows from phase to phase
- Fully equipped USP <797> and <795> pharmacy areas, adapted to phase of study
- Pharmacy manual development
- Adaptable doses during FIH design
- Small-scale GMP manufacturing
- Development, validation, stability, QC/QA/QP release
- Concurrent stability program as product advances through development
- GMP and GCP blinding
- SOP compliance to strictest regulations, including FDA, HPFB, EMA, MHRA, Anvisa

PROOF OF CONCEPT THROUGH COMMERCIALIZATION

- Final formulation
- Seamless CMC beyond early development
- Clinical manufacturing
- Packaging, labeling, and distribution
- Scale-up to commercialization
- Technology transfers/backup

INTEGRATED, PROACTIVE APPROACH TO CLINICAL SUPPLY MANUFACTURE

We simplify your program with an integrated, proactive approach to clinical supply manufacture. Formulation, manufacture, and clinical conduct work in tandem with data sharing, program timelines, and critical milestone synchronization.



BENEFITS OF INTEGRATED CRO/CDMO SERVICES

- Eliminate handoffs
- Reduce time between milestones
- Minimize logistical challenges
- Deliver an efficient, timely, and cost effective program progression

Our CDMO is ready to deliver all the way up to final formulation and commercialization. Scalable equipment ensures larger batches are manufactured to specifications, and we provide packaging, labelling, and distribution services for a holistic solution.